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Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Veterinary Services

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Report of Vaccine Forum
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This report was prepared from comments received and compiled by the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), and Veterinary Services (VS) during a forum held to consider vaccine-related issues in USDA disease eradication and control programs.

The forum was a cooperative effort between state and federal government, academia and the biologics industry personnel. We wish to thank all attendees for contributing their expertise and for their frank discussion of vaccine-related issues critical to eradication programs. We also thank the VS employees who were responsible for organizing this forum.

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Vaccine Forum Report

Background:

As we approach the eradication of specific animal diseases in the United States, it will be necessary to refine regulations, policies, and procedures pertaining to veterinary biological product availability for these diseases. In addition, eradication may require changes in the distribution of diagnostic reagents and diagnostic test kits or the establishment of vaccine banks.

In order to begin a process that will lead to decisions and policy around the use of vaccines in eradication programs, the Center for Veterinary Biologics (CVB) was asked to host a forum to obtain input from a variety of experts. Approximately 35 individuals from United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) Veterinary Services (staff, field, and laboratory personnel), the biologics industry, producer groups, and researchers were invited to attend the forum which was held October 20, 2002, in St. Louis, Missouri. Of this group, 27 individuals attended.

From the discussion at this forum, the group developed a list of issues which the group believed APHIS should consider when developing regulations or polices concerning the use of vaccines in eradication programs.

Summary of the Issues:

General comments:

• Before developing policy or regulations, USDA should seek input and support from state animal disease control officials and affected producers.

• Any policy developed should be flexible because it will apply to a variety of disease situations (examples cited were pseudorabies, brucellosis, avian influenza, Venezuelan equine encephalomyelitis, Newcastle disease, and perhaps other as yet unidentified diseases). Specific policies and regulations should be developed for each disease based on the issues pertaining to that disease.

• If a decision is made to discontinue the use of vaccines in an eradication program, a timeline should be developed so that vaccine manufacturers have sufficient notice to cease production.

• Although the planning and discontinuance process may take several years to implement, this forum was a useful tool for developing strategies for policy making.

Economics and trade considerations:
• The Office International des Epizooties (OIE) requirements concerning *International Animal Health Code* requirements for obtaining disease freedom should be followed closely in order to ensure that the new status is accepted by all trading partners.

• The group agreed that officials should consider the economics and trade implications before implementing vaccine use policies. One of these implications is that OIE disease-free status may not be possible if vaccination is continued. If a decision is made to continue vaccination for certain diseases beyond eradication, the reasons should be explained to trading partners.

• The USDA definition of "disease free" should be clear to trading partners and to industry. For example, "free" may mean "free in domestic livestock but not in wildlife" or "free" may mean "does not exist in the United States." The OIE Code definition of "disease freedom" should be a primary guideline.

• The possibility of regionalization or compartmentalization, as outlined in the OIE *International Animal Health Code*, may be an option for some diseases and should be considered.

• An economic risk assessment should be considered before regulations discontinuing vaccination are implemented. For example, is the cost of prevention and perhaps loss of exports (to producers) greater than the cost of control if the disease is reintroduced to a naïve population.

Disease characteristics:
• As part of any risk assessment, the potential for reintroduction of the disease should be considered. For example, does the disease exist in United States wildlife? If reintroduced, are surveillance systems adequate to promptly identify outbreaks or could the disease spread for a time without detection?

Vaccine characteristics:
The characteristics of the vaccine being used should be considered. For example:
• Vaccines that pose some safety or health risk should be discontinued as soon as possible (as was done with the live-virus hog cholera products). Safer vaccines could be used for as long as economically feasible.

• Vaccination could continue for a longer period if technology exists to distinguish vaccinated animals from diseased or exposed animals.

Biosecurity:
• Biosecurity will be an important consideration. Disease agents for which there are Veterinary Services (VS) eradication programs will appear on the USDA list of "high consequence" pathogens list and possibly the Department of Health and Human Services' "select" agent list. All movement of these agents will be under permit. Facilities that maintain live agents will have to meet requirements of any

biosecurity legislation.

• Biosecurity capabilities should influence any decisions on whether United States biologics firms will be allowed to produce antigens or vaccines for program disease agents once the United States is declared free of that agent.

• In the last stages of an eradication program, sales of vaccines should be restricted to veterinarians so that use can be monitored by Federal and state animal health officials.

Diagnosis concerns:

• We should have the ability to rapidly detect reintroduction of the disease in question before vaccination is eliminated.

• APHIS should encourage prolonged surveillance testing after eradication. Such surveillance testing will comply with requirements outlined in the OIE *International Animal Health Code* and will demonstrate that the disease has not been reintroduced and will serve to maintain expertise in diagnosis.

• The impact on the National Veterinary Services Laboratories and state diagnostic laboratories should be considered. Increased surveillance may strain the resources of these laboratories.

• Diagnostic test kits will be needed for surveillance testing long after a disease is declared eradicated. USDA should ensure availability of diagnostic test kits and reagents.

Concerns about vaccine availability:

• If vaccination is discontinued and a reintroduction does occur, demand for vaccine (perhaps millions of doses) will be immediate. APHIS should consider having a plan in place to allow for rapid importation of vaccine.

• Or, depending upon the disease agent, APHIS should establish a vaccine bank. The bank will need to have sufficient quantities of vaccine. Vaccines will need to be replenished as they are out dated. A rapid distribution plan should be developed. The establishment of vaccine banks for high consequence agents was strongly encouraged.

• For some diseases, it may be important to maintain vaccine production expertise in the United States. Once production ceases, knowledge is lost and advances in technology will not occur. For some diseases, APHIS could contract with a U.S. biologics manufacturer to produce vaccine for the bank. This would serve to maintain expertise as well as provide product for an emergency.

• If biocontainment issues can be adequately addressed, domestic vaccine producers should be allowed to continue production of vaccines for export only. Vaccine could then be diverted for domestic use in the event of an outbreak.

• The group suggested that APHIS discuss plans with vaccine manufacturers to

ensure that manufacturers do not discontinue production while products are still needed.

Recommendations:

• VS staff responsible for program diseases should include the development of vaccination policy in their eradication planning process. Discussions regarding vaccine discontinuance should include opportunities for input from interested parties, disease experts, and stakeholders.

• This group also suggested that APHIS sponsor meetings to discuss 1) the use of vaccines for Venezuelan equine encephalomyelitis and 2) biosecurity issues surrounding foreign animal disease agents.